REMARKS

Claims 1 and 14 have been amended. New claim 19 has been added.

Claim 14 has been rejected under 35 USC 112, first paragraph, as failing to comply with the written description requirement. The Examiner has found that the specification provides insufficient written description to support the genus of "somatostatin analogs" encompassed by the claim. However, claim 14 has been amended to delete the term "analog." Therefore, it is requested that the Examiner reconsider and withdraw the present rejection.

Claims 1 – 18 have been rejected under 35 USC 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The Examiner has found the term "at least one terminal segment derived from" is indefinite because it is unclear how far one can deviate from the parent compound. The Examiner also has found the term "somatostatin analog" is indefinite because it is unclear how far one can deviate from the parent compound. Accordingly, independent claim 1 has been amended to require that the terminal segment is obtained from the ring-opening polymerization" of at least one cyclic monomer. Similarly, claim 14 has been amended to delete the term "analog." Thus, is it requested that the Examiner withdraw the present rejection.

Claim 1 has been rejected under 35 USC 102(b) as being anticipated by EP 0952171. The Examiner argues that EP '171 discloses polyester copolymers and their utility in providing a protective barrier to prevent post-surgical adhesion, treatment of defects in conduits such as blood vessels, and controlled release of a biologically active

agent for modulating cellular events such as wound healing and tissue regeneration. The Examiner finds that the polymers are essentially the same as those set forth in the present claim and argues that the phrase "stent coating composition for multifaceted prevention of vascular restenosis through a plurality of physicopharmacological modes" is an intended use, and that a recitation of an intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art; that is, if the prior art structure is capable of performing the intended use, then it meets the claim. The Examiner argues that the composition disclosed by EP '171 is fully capable of being used as a stent coating as set forth in the present claim. However, EP '171 is directed to hydrogel-forming, self-solvating liquid copolymers. One of ordinary skill in the art would recognize that liquid polymers could not be used as necessarily solid coatings for endovascular stents. Accordingly, it is requested that the Examiner reconsider and withdraw the present rejection.

Claim 1 is rejected under 35 USC 102(b) as being anticipated by WO 9921908. The Examiner argues that WO '908 discloses biodegradable polymeric implants comprising at least one bioactive compound and a segmented copolymer comprising a central polyoxyethylene segment and at least one terminal segment obtained by the ring opening polymerization of lactide, glycolide, and/or caprolactone. The Examiner notes that the reference contemplates injecting the composition into the vascular wall at the same time and location that a stent is implanted. Thus, the Examiner finds that the composition disclosed by WO '908 is fully capable of being used as a stent coating in

accordance with the present claim. However, as above, the composition disclosed in WO '908 is a liquid; otherwise it would not be injectable. Liquid polymers are inappropriate for use as coatings in this application. Accordingly, it is requested that the Examiner reconsider and withdraw the present rejection.

Claims 1, 4, 11, 12, and 14 have been rejected under 35 USC 103(a) as being unpatentable over EP 0952171. The Examiner notes that EP '171 fails to disclose a specific combination of a basic antiangiogenic compound and an acidic non-steroidal anti-inflammatory but finds that it would be obvious to one of ordinary skill in the art to prepare a polymer as disclosed by EP '171 comprising an ionic conjugate of naproxen (an acidic non-steroidal anti-inflammatory) and a somatostatin analog (a basic antiangiogenic peptide) as EP '171 provides a polyester copolymer useful as a protective barrier to prevent post-surgical adhesion, treatment of defects in conduits such as blood vessels, and controlled release of a biologically active agent for modulating cellular events such as wound healing and tissue regeneration. However, as discussed above, the polyester copolymers of EP '171 would not be useful as the stent coating of the present claims as those polymers are liquid. Accordingly, it is requested that the Examiner reconsider and withdraw the present rejection.

Claims 1, 3, 4, and 9 – 16 have been rejected under 35 USC 103(a) as being unpatentable over EP 0952171 in view of US 2002/0041893. The Examiner notes that EP '171 fails to disclose introduction of at least one carboxyl end group by acylation of a terminal segment with glutaric anhydride and that EP '171 further fails to disclose lanreotide and trapidil ionically conjugated to the polymer. The Examiner finds that the

'893 reference discloses sustained release ionic conjugates which contain a free carboxyl group-containing biodegradable polymer and a free amino group-containing drug which are ionically bound to each other. In one embodiment the drugs are acid-stable peptides such as LHRH, somatostatin, and lanreotide. The carboxyl group is introduced into polyesters such as polylactic acid and polyglycolic acid by acylation with an appropriate agent, such as glutaric anhydride. The Examiner finds it would be obvious to one of ordinary skill in the art to combine EP '171 and '893 to afford the instant invention. Specifically, the Examiner finds it would be obvious to introduce a carboxyl group into the polymer of EP '171 through acylation of the terminal di-lactide/glycolide with glutaric anhydride as EP '171 contemplates acylation of the terminal di-lactide/glycolide with an appropriate agent. The Examiner further finds that it would be obvious to bind a combination of drugs to the polymer, such as lanreotide and trapidil, as both of these compounds meet the structural requirements of such binding (each has at least one free amine), and both compounds, lanreotide, an anti-restenosis agent, and trapidil, a vascodilator, are useful drugs to be administered in conjunction with a cardiac stent to prevent reocclusion of the blood vessel, or generally administered to promote wound healing. However, even with these drugs bound to thereto, the liquid polymer of EP '171 would not be useful as a stent coating in accordance with the present claims. Accordingly, it is requested that the Examiner reconsider and withdraw the present rejection.

Claims 1 – 4 and 9 – 16 have been rejected under 35 USC 103(a) as being unpatentable over EP 0952171 in view of US 2002/0041893 and further in view of US

Patent No. 5,149,747. The Examiner notes that EP '171 fails to disclose the introduction of at least one carboxyl side group by free-radically achieved maleation. The Examiner further notes the '893 discloses sustained release ionic conjugates which contain a free carboxyl group-containing biodegradable polymer and a free amino group-containing drug which are ionically bound to each other. The '747 patent is cited for disclosing that succinic anhydride, glutaric anhydride, and maleic anhydride are excellent acylating reagents for the preparation of esterified graft polymers. The Examiner argues that it would be obvious to one of ordinary skill in the art to combine the references to afford the instant invention; specifically that it would be obvious to introduce a carboxyl side group into the polymer disclosed by EP '171through free-radically achieved maleation. However, even if one were to introduce a carboxyl side group into the EP '171 in this manner and ionically bind the drugs disclosed in '893 thereto, the polymer would still be a liquid polymer, inappropriate for use as a solid stent coating. Accordingly, it is requested that the Examiner reconsider and withdraw the present rejection.

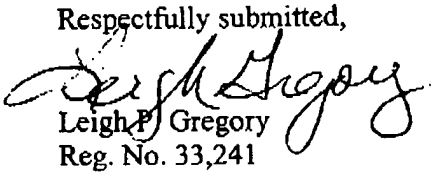
Claims 1, 4 – 8, and 17 and 18 have been rejected under 35 USC 103(a) as being unpatentable over WO 9921908. The Examiner acknowledges that WO '908 frails to disclose the specific combinations of bioactive agents set forth in the present claims 4 – 7 and further that WO '908 fails to disclose a stent coated with the polymer composition, but finds that it would be obvious to one of ordinary skill in the art to incorporate such combinations of agents into the composition disclosed by WO '908 as the reference teaches such combinations as embodiments that provide an effective drug delivery system that can be implanted within a subject. However, WO '908 actually teaches

injection of its liquid polymer composition into the vascular wall. Even with a desirable combination of drugs bound thereto, the liquid polymer of WO '908 is inappropriate for use as the present stent coating. Accordingly, it is requested that the Examiner reconsider and withdraw the present rejection.

Thus, it is submitted that the present case is in condition for allowance and such action is respectfully requested.

Please address all correspondence to the below-indicated address.

Respectfully submitted,



Leigh P. Gregory
Reg. No. 33,241

9-26-08

P.O. Box 168
Clemson, SC 29633-0168
757-642-6039